July 13, 2004

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Interim Final Regulations of PL 107-188:
Prior Notice of Imported Food – Docket No. 02N-0278

Dear Sir or Madam:

The International Bottled Water Association (IBWA)[1] submits additional comments to the U.S. Food and Drug Administration (FDA) on the interim final regulations on prior notice of food importation that implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. No. 107-188). These comments are in addition to the comments submitted by IBWA on May 14, 2004.

IBWA is dedicated to helping ensure the safety and quality of bottled water and is committed to preventing potential adverse events, both natural and man-made, through monitoring and testing, risk assessment, risk management, appropriate controls and procedures, and due diligence. IBWA and FDA share the goal of reducing bottled water security risks and hopefully can work together to meet that goal. IBWA is encouraged by the efforts of FDA to enter into a dialogue with the bottled water industry on addressing security issues.

I. Summary of Comments

In addition to the comments previously submitted to FDA, IBWA believes that the following recommendations will improve the workability and compliance with the regulations, while maintaining the letter and spirit of the Bioterrorism Act. Specifically, IBWA urges FDA to:

1. **Provide flexibility for identifying the manufacturer of food product samples that will be used for research and development for purposes of prior notice; and**

[1] IBWA is the trade association representing all segments of the bottled water industry. Founded in 1958, IBWA member companies includes U.S. and international bottlers, distributors and suppliers. IBWA is committed to working with state and federal governments, in concert with the IBWA Model Code, to set stringent bottled water standards for safe, high quality products. As a condition of membership, IBWA bottlers must submit to an annual, unannounced inspection for compliance with the Model Code by an independent third party.

2. **Work with the Bureau of Customs and Border Protection (CBP) to develop a product code that identifies samples, particularly samples for analytical purposes that do not require prior notice.**

II. Docket No. 02N-0278 – Prior Notice for Food Importation

IBWA Comments

Greater Flexibility in Identifying Manufacturer of Food Samples

IBWA urges FDA to develop greater flexibility in the information required for samples of food products that are imported for purposes of research and development. Specifically, a food facility registration number should not be required for food samples that are imported for purposes of research. Alternatives should be developed to provide identification of the name and address of the manufacturer, and the responsible importer.

Samples of bottled water are imported for a variety of research and development analyses. The actual manufacturer's food registration number may not exist, since the decision to import their brand of bottled water may not yet have been made. The cost of establishing a United States agent and registering/maintaining the foreign food facilities registrations may not be practical if the decision to import has not been made. Finished product may be subjected to laboratory analysis, as well as consumer taste panels. Thus, it would not qualify for the "dual use" exemption as provided for food products not intended for human consumption.[2]

The Bioterrorism Act does not specifically require the use of the manufacturer's food facility registration number, but arguably permits FDA latitude for developing a method for identifying the manufacturer of a sample food product, which is not intended for public consumption or sale. Such alternatives could include the following options:

- The manufacturer's registration number could be replaced by other identifying information such as the manufacturer's name and address;
- The manufacturer's registration number could be replaced by the registration number of the importing manufacturer who is ultimately responsible for the shipment and final use of the product;
- FDA could require registration numbers for **either** shipper or manufacturer. This alternative would provide FDA with information to enable enforcement of foreign facility registration without imposing unnecessary and unobtainable information burdens; it would also allow a U.S. manufacturer to recall product to the U.S. when necessary without unnecessarily registering a "shipper."

Any alternative would require only a simple technology adjustment to identify a specific shipment as: "samples for research and development." Thus, processing at the

[2] Guidance to Industry - Prior Notice of Imported Food Questions and Answers(Edition 2), May 2004

borders of samples of food products would be facilitated and minimize the impact of the prior notice regulations on imported food samples. Without such flexibility, the impact on United States testing laboratories could be significant. Foreign companies, who currently use United States laboratories, may seek Canadian or other foreign laboratories to do their analysis.

Sample Identification

For "dual use" products, such as water samples for analytical testing, a code needs to be developed so that the products can be readily identified and move smoothly through entry into the United States. This product code(s) will clarify the contents as not intended for human consumption and eliminate any confusion at the border on the need for prior notice.

During the initial implementation of the interim final regulation, CBP and FDA have been collecting and analyzing data on compliance with the prior notice requirements. However, IBWA is concerned about how samples have been reviewed and the potential for "misidentified" samples. In some cases since the first of the year, samples of water for analytical purposes that do not require prior notice according to the Guidance to Industry Edition 2 have been held on entry for failure to provide prior notice because of a lack of specific coding for such water samples. If the customs documents indicate the shipment contents as water samples of no commercial value, there is no current method of identifying the samples as not requiring prior notice. Adding a specific code to the FDA products code builder for such samples should be a relatively easy solution and result in consistent application of the prior notice requirements to all U.S. ports.

Recommendations

IBWA urges FDA to continue and improve the coordination with Customs and Border Protection. The closer harmonization there is between the requirements for prior notice, the more efficient and less confusion there will be among all parties involved in international trade. By synchronizing the timelines, compliance will be improved when food products are shipped with non-food products.

IBWA urges FDA to use its discretion and not require the food facility registration number for food samples. Flexibility in the method for identifying the product manufacturer and the responsible parties would both provide industry with options while adhering to the spirit, if not the letter, of the Bioterrorism Act.

In this regard, FDA has publicly stated that it will "actively consider the exercise of its discretion in the enforcement of the Prior Notice interim final rule."[3] IBWA does not believe that Congress intended this regulation to apply to the importation of bottled and source water samples for testing analysis, which are intended for neither human nor animal consumption.

[3] *See FDA's Fact Sheet on FDA's New Food Bioterrorism Regulation: Interim Final Rule – Prior Notice of Imported Food Shipments,* at http://www.cfsan.fda.gov/~dms/fsbtac13.html (last viewed Dec. 1, 2003).

IBWA requests FDA review of the product codes and develop codes for products that are "dual use," but not intended for human or animal consumption, as well as food samples that are intended for research and development purposes. This will provide an easy reference for FDA and CBP staff and all those involved in the importation of bottled water. It will also reduce conflicts over the need for prior notice for specific shipments of water samples for analytical testing and those samples which may use an alternative identification method for the manufacturer of the food product.

IV. Conclusion

IBWA looks forward to working with FDA in implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In addition, IBWA appreciates the efforts put forth by FDA in promulgating the interim final regulations and now permitting the opportunity to provide additional comment on the interim rules. IBWA pledges our continued educational outreach to assist the bottled water industry in complying with the regulations and ensuring a safe, quality bottled water for the consumers.

If you need further information or have any questions, please do not hesitate to contact IBWA or me at (703) 683-5213 ext. 108, or at pdonoho@bottledwater.org.

Sincerely,

Patrick B. Donoho

Patrick B. Donoho
Vice President, Government Relations